

TITLE: APPARATUS FOR MEASURING HEMODYNAMIC PARAMETERS
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CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This is a continuation application of application serial no. 10/134,356, filed on April 27, 2002, which is a continuation of application serial no. 09/732,274, filed on December 7, 2000, now U.S. Patent No. 6,428,478, which is a divisional of application serial no. 09/315,867 , filed on May 29, 1999, now U.S. Patent No. 6,221,021, which is a continuation in part application of application serial no. 08/926, 209, filed on September 9, 1997, now U.S. Patent No. 5,947,901.

BACKGROUND OF THE INVENTION

1. Field of The Invention

[0002] The present invention is directed toward an ultrasonography apparatus for measuring and/or monitoring hemodynamic activity, such as blood flow. The present invention comprises a doppler ultrasound unit, one or more transducers, and a portable body.

2. Description of The Prior Art

[0003] Erectile dysfunctionality may result from neurogenic, vasculogenic, hormonal, and/or psychogenic causes. The term “erectile dysfunctionality”, as used herein, refers to the inability or impaired ability of a male patient to experience a penile erection. The urological arts have developed a number of therapies for treating erectile dysfunctionality. These therapies include psychological, pharmacological, and electrical therapies.

[0004] A method and device for electrically stimulating a penile erection is disclosed in U.S. Patent No. 4,585,005 to Lue et al. The method disclosed in Lue includes the implantation of an electrode on the cavernous nerve. The electrodes of Lue are connected to a receiver that is subcutaneously implanted in the patient. The method and device disclosed in Lue requires surgery. Additionally, if the device disclosed in Lue malfunctions, surgery is required to remove it. Surgery is expensive and time consuming. Additionally, many patients may have emotional or psychological aversions to having electrodes implanted in their penis.

[0005] An apparatus for electrically stimulating penile tissue to cause a penile erection is disclosed in U.S. Patent No. 5,571,118 to Boutos. Boutos discloses the use of a ring having a conductive surface that is placed on the penis and/or the scrotum. There exists a risk that such

1 a device may short circuit, if used in an electrically conductive environment, such as a hot
2 tub. This is a major drawback of external electrical therapies, as contrasted with external
3 ultrasound therapies. The use of ultrasound transducers on submerged patients has been
4 applied in other nonanalogous arts, such as extracorporeal shock wave lithotripsy.

5 [0006] An apparatus for electrically stimulating a penile erection is disclosed in U.S. Patent
6 Nos. 4,542,753 and 4,663,102 to Brennan et al. Brennan discloses a body member for
7 insertion into the rectum of a patient. The body member comprises surface mounted
8 electrodes. Brennan teaches insertion of the body member sufficiently deep into the patient
9 for at least one electrode to contact the prostate gland. The device disclosed by Brennan is
10 highly invasive. Patients may experience physical discomfort from the rectal insertion of
11 the device disclosed in Brennan.

12 [0007] Pharmacological therapies for erectile dysfunction include the injection of drugs
13 into the penis. Such methods are disclosed in U.S. Patent Nos. 5,236,904 to Gerstengerg
14 et al. and 4,127,118 to Latorre. Many male patients find the thought of jabbing a
15 hypodermic needle into their penis to be discomforting. Penile injections may also result
16 in the buildup of scar tissue, bleeding, and persistent prolonged erection (priapism). The
17 unacceptability of therapies requiring the intracavernosal injection of drugs into the penis
18 is well documented in the urological arts (See U.S. Patent Nos. 5,482,039 to Place et al.
19 and 5,731,339 to Lowrey; and Padma-Nathan, *Treatment of Men With Erectile Dysfunction*
20 *With Transurethral Alprostadil*, The New England Journal of Medicine, 336:1-7, January
21 2, 1997).

22 [0008] Other pharmacological therapies for erectile dysfunction include delivering a
23 drug directly into the urethra of a patient. Methods and devices for transurethral delivery
24 of drugs into the penis are disclosed in U.S. Patent Nos. 5,242,391 and 5,482,039 to Place
25 et al. These transurethral drug delivery methods involve inserting a shaft into the urethra.
26 The insertion of a shaft up the urethra may cause discomfort in many patients or be
27 objectionable for many of the same reasons that penile hypodermic needle injections are
28 objectionable.

29 [0009] Pharmacological agents for the treatment of erectile dysfunction, including

1 vasodilators such as phosphodiesterase (PDE) inhibitors, or alpha adrenergic blockers, may
2 also be delivered orally, transmucosally, transdermally, intranasally and/or rectally. Oral
3 medications are available, pursuant to U.S. Food & Drug Administration (FDA)
4 regulations, under the trademarks VIAGRA (a PDE inhibitor) from Pfizer, Inc. of New
5 York, N.Y., and VASOMAX (an alpha adrenergic blocker) from Zonagen, Inc. of The
6 Woodlands, Texas, or its licensees. Such oral medications are described in U.S. Patent
7 Nos. 5,731,339 to Lowrey and 5,565,466 to Gioco, et al.

8 [0010] Orally, transmucosally, transdermally, intranasally, and/or rectally ingested
9 pharmacological agents for the treatment of erectile dysfunction must be dissolved into
10 the blood stream and transported through the body to the penis. Methods of transporting
11 such pharmacological agents to a desired site of effect, are disclosed in U.S. Patent No.
12 5,565,466 and are incorporated herein, in their entirety. The time required for such
13 pharmacological agents to be dissolved into the blood stream and transported to a site where
14 they will relax the smooth muscle tissue in the corpora cavernosa, resulting in increased
15 penile hemodynamic activity sufficient to cause an erection (referred to herein as the
16 “circulatory medication response time”), can be as long as one hour. This time period can
17 be unsatisfactory to many men and their consorts, who desire spontaneity in their sexual
18 relations.

19 [0011] The present invention provides an ultrasonic therapy for hemodynamic stimulation
20 of the penis that does not require (1) the injection of drugs into the penis, (2) surgical
21 implantation of electrodes into the penis, or (3) the insertion of electrodes into the rectum.
22 The method of the present invention may be used in an electrically conductive medium, such
23 as a pool or hot tub, without the short circuiting risk present in prior art methods of
24 electrotherapy for penile dysfunction. The present invention may be used to reduce the
25 circulatory medication response time by accelerating the circulation of blood comprising a
26 vasoactive or vasodilating agent, thereby reducing its transport time.

27 **SUMMARY OF THE INVENTION**

28 [0012] Blood is the hydraulic driving fluid that provides the mass increase and force which
29 result in a penile erection. Under normal conditions, a penile erection occurs when the mass

1 flow rate of blood into the penis exceeds the mass flow rate of blood out of the penis for a
2 certain time interval. Vasculogenic erectile dysfunction may result from a restriction
3 or blockage of blood flow into the penis or from excess blood flow out of the penis. The
4 present invention is aimed at treating vasculogenic erectile dysfunction that results from
5 inadequate blood flow into the penis.

6 [0013] The present invention provides a method for stimulating hemodynamic activity
7 within a penis. The first method step of the present invention is coupling an ultrasound
8 source to a penis. Genital lesions, such as warts or herpes simplex Type - 2 lesions, can
9 absorb and/or attenuate ultrasound thereby reducing the therapeutic effectiveness of the
10 present invention. Accordingly, in a preferred embodiment, the ultrasound source is
11 coupled to a lesion free region of the outer surface of a penis.

12 [0014] The second method step of the present invention is transmitting ultrasound energy
13 into the corpora cavernosum of the penis at a sufficient frequency and intensity to increase
14 hemodynamic flow within the penis. The frequency used is a function of the depth of
15 desired penetration into the corpora cavernosum.

16 [0015] Initially, a frequency in the range of 2.5 - 3.5 MHz is desirable. As hemodynamic
17 activity in the penis increases and the penis expands circumferentially, it is desirable to
18 reduce the frequency of ultrasound energy from the initial frequency to a reduced frequency
19 in the range of 1.8 - 2.5 MHz. The precise values of initial and reduced frequencies will
20 be a function of the diameter of the penis being treated.

21 [0016] A portion of the ultrasound energy transmitted into the body is converted to thermal
22 energy. The increased blood flow resulting from the use of the present invention provides
23 a thermal transport medium for transporting and dispersing thermal energy introduced from
24 the transmission of ultrasound energy. This thermal transport helps to minimize localized
25 temperature increases within the penis. In a preferred embodiment, the ultrasound energy
26 is emitted from one or more ultrasound transducers housed within a portable housing.
27 Localized temperature increases can be further minimized by moving the portable housing
28 relative to the penis being treated so as to disperse the transfer of thermal energy in the
29 corpora cavernosum.

1 [0017] The present invention also provides a method for monitoring the effect of the
2 stimulation therapy of the present invention. The present invention also includes
3 ultrasonographically measuring one or more hemodynamic parameters within the penis.
4 These hemodynamic parameters may include blood flow velocity, blood pressure, and/or
5 blood temperature. The measured hemodynamic parameters can be graphically displayed
6 to provide a real time indication of hemodynamic and/or thermal-hydraulic parameters
7 within the penis. The measured hemodynamic parameters may be transmitted to a remote
8 terminal for analysis by a remotely located health care professional. Alternatively, the
9 measured hemodynamic parameters may be analyzed by an expert system located either
10 remotely or with the patient.

11 [0018] The present invention is also directed toward an apparatus for stimulating
12 hemodynamic activity within a penis. The apparatus of the present invention comprises an
13 ultrasound generator, and a portable housing coupled to the ultrasound generator. The
14 housing comprises at least one ultrasound trigger and a first transducer mounting assembly.

15 [0019] The apparatus of the present invention may also be used to ultrasonographically
16 measure and/or display one or more hemodynamic parameters.

17 **DESCRIPTION OF THE DRAWINGS**

18 [0020] Figure 1A is a block diagram of a first method embodiment of the present invention.

19 [0021] Figure 1B is a block diagram of a second method embodiment of the present
20 invention.

21 [0022] Figure 2 is a front view of a first apparatus embodiment of the present invention.

22 [0023] Figure 3 is a block diagram of a second apparatus embodiment of the present
23 invention.

24 [0024] Figure 4 is a side cross sectional view of the rotatable adjusting wheel of the present
25 invention.

26 **DESCRIPTION OF THE PREFERRED EMBODIMENTS**

27 [0025] The apparatus of the present invention comprises an ultrasound generator 8 and a
28 portable housing 10 coupled to the ultrasound generator, as shown in Figure 2. The
29 portable housing comprises a first transducer mounting assembly 18. In a preferred

1 embodiment, the first transducer mounting assembly is curved. An ultrasound trigger 11
2 is mounted in the housing and electrically coupled to the generator.

3 [0026] In a preferred embodiment, the ultrasound generator is capable of selectively
4 generating pulsed or continuous wave ultrasound energy. This selective generation may be
5 accomplished by a control knob or switch 7, as shown in Figure 2. In a preferred
6 embodiment, the ultrasound generator further comprises frequency controls 6 and intensity
7 controls 7, as shown in Figure 2. In a preferred embodiment, the ultrasound generator is
8 capable of generating ultrasound energy within a frequency range of 1.8 - 3.5 MHz and
9 within an intensity range of 1.0 - 2.0 watts/square centimeter.

10 [0027] In a preferred embodiment, a position adjuster is coupled to the first transducer
11 mounting assembly. In the preferred embodiment shown in Figures 2 and 4, the adjuster
12 comprises a threaded rod 14 and a rotatable adjusting wheel 16, comprising a centrally
13 located female threaded channel 17. The channel threadably engages the rod such that when
14 the wheel is rotated, the rod is axially displaced.

15 [0028] It is known in the ultrasound arts that a satisfactory ultrasound coupling is necessary
16 for effective delivery of ultrasound energy to a patient for therapeutic or diagnostic
17 purposes. The position adjuster provides a mechanism for maintaining a satisfactory
18 ultrasound coupling as the penis expands circumferentially as a result of increased
19 hemodynamic activity. As shown in Figure 2, the position adjuster can be used to control
20 the separation distance between the first and second mounting assemblies, 18 and 24. The
21 position adjuster also makes the present invention suitable for use with different patients
22 having varied physical sizes.

23 [0029] The apparatus and method of the present invention may be practiced by the patient,
24 after proper training, without assistance from another person. In the preferred embodiment
25 shown in Figure 2, the portable housing has a pistol type grip, thereby allowing the user to
26 operate the trigger or triggers with one hand, while manipulating the position adjuster with
27 the other hand, as needed to maintain a suitable ultrasound coupling during penile
28 expansion. The placement of the triggers and axial position adjuster on opposite sides of
29 the housing facilitates the user's ability to easily use both hands to simultaneously

1 manipulate the trigger and the position adjuster.

2 [0030] In a preferred embodiment, the invention further comprises an second transducer
3 mounting assembly 24 mounted across from the first transducer mounting assembly. In a
4 preferred embodiment, the second transduced mounting assembly is mounted in alignment
5 with the first transducer mounting assembly. In another preferred embodiment, the second
6 transducer mounting assembly is curved. The second transducer mounting assembly is
7 coupled to the position adjuster. In a preferred embodiment, the radii of curvature of the
8 first and second transducer mounting assemblies are sized such that the first and second
9 transducers can be coupled to the outer surface of a penis.

10 [0031] A first ultrasound emitter 19 is mounted in the first transducer mounting assembly.
11 The first transducer is connected to the ultrasound trigger and to the ultrasound generator.
12 Electrical and/or electronic circuitry suitable for connecting ultrasound transmitters to an
13 ultrasound generator are described in the following U.S. Patents: 3,735,756 to Richards;
14 5,578,060 to Pohl et al.; and 4,484,569 to Driller et al. The full disclosures of these U.S.
15 Patents is incorporated herein by reference.

16 [0032] A second ultrasound transducer 22 is mounted in the second transducer mounting
17 assembly, as shown in Figure 2. The second ultrasound emitter is connected to the
18 ultrasound trigger and to the ultrasound generator. In a preferred embodiment, the first and
19 second ultrasound emitters comprise a multiplicity of transducers, as shown in Figure 2.

20 [0033] In the preferred embodiment shown in Figures 2-3, the invention further comprises
21 an ultrasonography generator 30 connected to at least one transducer in each transducer
22 mounting assembly and an ultrasonography trigger 12 mounted in the portable housing and
23 connected to the ultrasonography generator. In a preferred embodiment the ultrasonography
24 generator and the ultrasound generator are each connected to at least two ultrasound
25 transducers in each of the transducer mounting assemblies. In a preferred embodiment the
26 ultrasonography generator is a doppler ultrasound unit.

27 [0034] The ultrasonography generator is suitable for monitoring penile hemodynamic
28 parameters, such as blood flow. Ultrasonographic apparatus suitable for use with the
29 present invention are disclosed in the following U.S. Patents: 4,612,937 to Miller; and

1 4,334,543 to Fehr. The full disclosures of these two patents are incorporated herein by
2 reference. In a preferred embodiment, the ultrasonography generator may comprise a
3 display 32 for displaying measured hemodynamic parameters and/or an expert system 33
4 capable of analyzing measured hemodynamic parameters. The expert system is capable of
5 comparing one or measured hemodynamic parameters to preestablished parameter limits,
6 such as maximum blood pressure or maximum blood temperature. The expert system is
7 further capable of generating an instruction to the user to stop ultrasound therapy if
8 predetermined parameter limits are exceeded. These instructions may be generated via the
9 display on the ultrasonography generator or by other visual or audible means of
10 communication.

11 [0035] In another embodiment, the expert system is capable of generating an open circuit
12 signal to the ultrasound generator in the event that preestablished limits are exceeded for
13 selected hemodynamic parameters. In this embodiment, the expert system functions as a
14 control circuit for the ultrasound generator. In a preferred embodiment, measured
15 hemodynamic parameter data may be transmitted to a remote location by a variety of data
16 transmission means, including telephone lines and wireless communication.

17 [0036] The present invention also provides a method for stimulating hemodynamic activity
18 within a penis, as shown in Figures 1A-1B. The method comprises coupling an ultrasound
19 source to the outer surface of a penis, as shown in block 40 of Figure 1A. In a preferred
20 embodiment the source of ultrasound energy is coupled to a lesion free region on the outer
21 surface of the penis. In a preferred embodiment the source of ultrasound energy comprises
22 at least two ultrasound transducers, placed on opposite sides of the penis, as shown in Figure
23 2. In another preferred embodiment the source of ultrasound energy comprises a portable
24 housing comprising the transducers.

25 [0037] The method further comprises transmitting ultrasound energy into the corpora
26 cavernosum of the penis at a sufficient frequency and intensity to increase hemodynamic
27 flow within the penis, as shown in block 42 of Figure 1A. It is known in the ultrasound arts
28 that 1 MHz ultrasound has a half value layer of 3.0 cm in muscle, while 3 MHz ultrasound
29 has a half value layer of 1.0 cm in muscle. The term "half value layer", as used herein

1 refers to the distance that ultrasound energy travels in a medium before half of the energy
2 is absorbed. The half value layers of various ultrasound frequencies in muscle are disclosed
3 in U. S. Patent No. 5,413,550 to Castel. It is desirable that the frequency used be such that
4 its half value layer will be less than the diameter of the penis being treated. In a preferred
5 embodiment of the present invention, the frequency is adjusted such that it has a half value
6 layer of less than the diameter of the penis being treated, as the penis expands
7 circumferentially, as shown in blocks 46 and 48 of Figure 1A. In a preferred embodiment,
8 the ultrasound energy should be applied at an intensity or power density of 1.0 - 2.0
9 watts/square cm.

10 [0038] The transmission of ultrasound energy may be either pulsed or continuous. In a
11 preferred embodiment the invention further comprises restricting the venous outflow of
12 blood from the penis, as shown in block 44 of Figure 1A.

13 [0039] In another preferred embodiment the invention further comprises
14 ultrasonographically measuring one or more hemodynamic parameters within the penis, as
15 shown in blocks 50 and 66 of Figures 1A and 1B, respectively. In a preferred embodiment,
16 the ultrasonographic measuring may be performed with a doppler ultrasound unit.

17 [0040] In a preferred embodiment the ultrasonographic measuring comprises a measurement
18 of blood flow velocity or blood pressure. In another preferred embodiment the transmitting
19 and measuring steps are performed in alternating series. In a preferred embodiment, the
20 invention further comprises displaying said measured hemodynamic parameters, as shown
21 in block 52 of Figure 1A.

22 [0041] The present invention is also directed to method for accelerating the delivery of a
23 vasodilating agent to produce a penile erection as shown in Figure 1B. This embodiment
24 of the invention comprises ingesting a vasodilating agent into the body at a point of
25 ingestion external to the penis, as shown in block 60 of Figure 1B. In a preferred
26 embodiment, the vasodilating agent is a PDE inhibitor or an alpha adrenergic blocker. In
27 another preferred embodiment, the vasodilating agent is phentolamine mesylate,
28 phentolamine hydrochloride, phenoxybenzamine yohimbine, organic nitrates, thymoxamine,
29 imipramine, verapamil, isoxsuprine, naftidrofuryl, tolazoline, or papaverine. In a preferred

1 embodiment the ingesting is transmucosal, transdermal, intranasal, or rectal ingesting. In
2 another preferred embodiment, the ingesting is oral.

3 [0042] The invention further comprises coupling an ultrasound source to a lesion free region
4 of the outer surface of a penis, as shown in block 62 of Figure 1B. The invention further
5 comprises transmitting ultrasound energy into the corpora cavernosum of the penis at a
6 sufficient frequency and intensity to increase hemodynamic flow within the penis, as shown
7 in block 64 of Figure 1B.

8 [0043] The embodiments of the invention disclosed herein are illustrative and explanatory.
9 Various changes in size, shape, material, as well as in the details of construction illustrated
10 herein may be made without departing from the scope of the invention.